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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/700,177 | 01/29/2001 | Ake Lindahl | 003300-696 | 2132 |

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 10/22/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------|------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/700,177 | AKE LINDAHL | |
| | Examiner Blessing M. Fubara | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 25 July 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-40 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment B and formal drawings filed 07/25/02.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendments.

However, new claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 30, the term "type" in "acrylic or acrylamide type" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "type"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

2. Claims 1-5, 8-14, 17, 22-25, 30 and 33-38 remain rejected under 35 U.S.C. 102(e) as being anticipated by Farinas et al. (US 5,906,830).

Applicants argue that the method of Farinas uses heat to create the supersaturation and that in the application supersaturation is brought about by chemical reaction/operation.

3. Applicant's arguments filed 07/25/02 have been fully considered but they are not persuasive because the claimed invention is to composition and not to the process of preparing the supersaturated state.

Applicants may claim the process if that is applicants' invention.

Farinas discloses a method for preparing transdermal drug delivery systems containing supersaturated drug reservoirs (abstract). The drug is heated to a temperature just higher than the calculated depressed melting temperature (column 6, lines 12-21). Farinas discloses that an amount of drug molecule is dispersed in the reservoir material at a concentration that is greater than the solubility of the drug in the reservoir material at room temperature to give a supersaturated drug reservoir (column 5, lines 1-10). The components of the reservoir include polymeric materials selected from polysiloxanes, polyacrylates and polyurethane adhesives (column 6, line 61 to column 7 line 24). Drugs that may be incorporated in the drug delivery system are narcotic agonists and antagonists, serotonergic agonists, antihistamines, anti-inflammatory agents, benzodiazepines, dopaminergic agonists and antagonists, hormones and antipsychotic agents (column 7, lines 39-64). The drug formulation further includes carriers or vehicles selected from stabilizers, antioxidants, anti-irritants, cellulosic polymers, polyvinyl alcohol and polyacrylic acid. See also claims 1-14. The teachings of Farinas anticipate the claims.

4. The rejection of claims 1, 17-20, 23-24 and 29 under 35 U.S.C. 102(b) as being anticipated by Lindahl (WO 97/00670) is withdrawn

Claim Rejections - 35 USC § 103

5. Claims 1-7, 22-28, 30 and 33-35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Farinas et al. (US 5,906,830).

Applicants argue that the supersaturated state is produced by chemical process while the supersaturated state in the prior art is produced by heat.

6. Applicant's arguments filed 07/25/02 have been fully considered but they are not persuasive because applicants have not claimed a process and it is not critical how the supersaturated state is formed except there is a showing of unexpected result. Applicants may claim the process of preparing the supersaturated state involving the proper method steps.

The method of Farinas comprises mixing polymeric material and a drug formulation, removing the most of the solvent, evaluating the depressed melting temperature of the drug-polymer mixture, heating the mixture to a predetermined temperature and cooling the heated mixture to form the supersaturated reservoir (claim 1). The invention does not teach any particular method steps. However, the prior art is silent on the degree of saturation. Degree of saturation is relative. One having ordinary skill in the art would have been motivated to prepare a supersaturated drug delivery reservoir according to the method of Farinas. In the absence of evidence to the contrary, the supersaturated drug reservoir is as supersaturated as the drug formulation of the invention.

7. The rejection of claims 1-29 under 35 U.S.C. 103(a) as being unpatentable over Lindahl (WO 97/00670) is withdrawn in light of the arguments presented by applicants.

Double Patenting

8. Claim 1 remains provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 2 of co-pending Application No. 09/700,176. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Applicants have asked that this rejection be held in abeyance until one of the patent issues but the rejection is maintained not withdrawn.

9. Claims 1-40 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of co-pending Application No. 09/700,176. Although the conflicting claims are not identical, they are not patentably distinct from each other because although the invention recites that the saturation of the saturation of the biologically active agent in the carrier matrix is higher than in the starting carrier, in the absence of indicating what the higher degree of saturation is, the invention is obvious over the supersaturated composition of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Although applicants have asked that this rejection be held in abeyance, the rejection is maintained.

10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification including the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

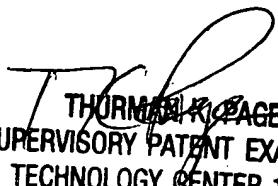
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
October 19, 2002



THURMAN R. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600